



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/529,234 | 04/06/2000 | TSUTOMU AWAMURA | 49668(281) | 1287 |

7590 12/17/2001

DIKE, BRONSTEIN, ROBERTS & CUSHMAN
Intellectual Property Practice Group
EDWARDS & ANGELL
P. O. Box 9169
BOSTON, MA 02209

EXAMINER

WHITE, EVERETT NMN

ART UNIT PAPER NUMBER

1623

DATE MAILED: 12/17/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/529,234

Applicant(s)

AWAMURA ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 10 is objected to because of the following informalities: The comma at the end of Claim 10 should be changed to a period. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "rapidly soluble" in claims 1-11 is a relative term which renders the claim indefinite. The term "rapidly soluble" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwakura et al (US Patent No. 4,777,046).

The Iwakura et al patent discloses a composition in form of a film which comprises, along with other ingredients, a drug; a polyhydric alcohol that may^{be} selected as sorbitol; and base components that may^{be} selected as a cellulose derivative that include ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and polyvinyl pyrrolidone. See column 2, 5th paragraph of the Iwakura et al patent wherein the proportion of the drug based on the total weight of the essential constituents is 0.01 to 50 w/w % and the proportion of the polyhydric alcohol is 1 to 50 w/w %. See column 2, lines 50-51 wherein the proportion of the other components which may be selected as the cellulose derivatives is 0 to 30 w/w %. The above information of the Iwakura et al patent anticipates the instantly claimed rapidly soluble film preparation of Claims 1-3 and 5-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwakura et al (US Patent No. 4,777,046) in view of Miranda et al (US Patent No. 5,656,286).

Applicants claim a rapidly soluble film preparation mainly comprising a drug, an edible polymer and a saccharide.

The Iwakura et al patent discloses a composition in form of a film which comprises, along with other ingredients, a drug; a polyhydric alcohol that may^{be} selected as sorbitol; and base components that may^{be} selected as a cellulose derivative that include ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and polyvinyl pyrrolidone. See column 2, 5th paragraph of the Iwakura et al patent wherein the proportion of the drug based on the total weight of the essential constituents is 0.01 to 50 w/w % and the proportion of the polyhydric alcohol is 1 to 50 w/w %. See column 2, lines 50-51 wherein the proportion of the other components which may be selected as the cellulose derivatives is 0 to 30 w/w %. The Iwakura et al patent further disclose a number of drug compounds that can be used with of the composition thereof that include indomethacin, lidocaine, tetracaine, procaine, tracycline, nitroglycerin, isosorbide dinitrate, propranolol, nifedipine, insulin, tripeleennamine, cyproheptadine, etc.

(see the last paragraph in column 1). The instant claims differ from the Iwakura et al patent by specifically reciting the drug nilvadipine that is not mentioned in the Iwakura et al patent. However, the Miranda et al patent suggests that the preparation of films comprising all of the above named drug compounds, including nilvadipine, alone with an edible polymer (such as PVP) is well known in art. The Miranda et al patent teaches that the use of soluble polyvinylpyrrolidone (PVP) results in the ability to form a film that does not contain particles of insoluble PVP and in the ability to employ higher concentrations of drug without resulting in increase crystallization of the drug (see column 3, 3rd paragraph). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the drugs used in the polyvinylpyrrolidone containing composition of the Iwakura et al patent with nilvadipine, in view of the recognition in the art, as evidenced by the Miranda et al patent, that polyvinylpyrrolidone is effective in increasing concentration of drug without resulting in increase crystallization of the drug.

Summary

All the claims are rejected.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EVERETT WHITE whose telephone number is 308-. The examiner can normally be reached on 703-308-4621 from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

Art Unit: 1623

supervisor, GARY GEIST, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703)305-3230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

E. White



GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600